Office of Compensation Analysis and Support	Document Number: OCAS-PR-004 Effective Date: 9/23/2004 Revision No. 0
Internal Procedures for the Evaluation of Special Exposure Cohort Petitions	Page 1 of 37
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RECORD OF ISSUE/REVISIONS

ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
9/23/2004	9/23/2004	0	New document to establish the requirements for processing Special Exposure Cohort Petitions

1.0 PURPOSE

The purpose of these internal procedures is to provide general guidance for the staff of the Office of Compensation Analysis and Support (OCAS) and its technical support contractors concerning procedures to evaluate Special Exposure Cohort (SEC) petitions. These internal procedures supplement the procedures described under 42 CFR Part 83, related procedures and guidelines for dose reconstruction described under 42 CFR Part 82, and related dose reconstruction implementation guidelines (OCAS-IG-001, 002, and OCAS-PR-002).

2.0 SCOPE

This document applies to all SEC petitions processed by NIOSH and its support contractor.

3.0 REFERENCES

3.1 42 CFR 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p 22314

3.2 42 CFR 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol. 69, No.104/Friday May 28, 2004, p 30764

3.3 NIOSH, (2002) *External Dose Reconstruction Implementation Guideline*, OCAS-IG-001, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

3.4 NIOSH, (2002) *Internal Dose Reconstruction Implementation Guideline*, OCAS-IG-002, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio

4.0 RESPONSIBILITIES

Described in procedure

5.0 GENERAL

These recommended procedures do not create any substantive rights on the behalf of petitioners. Comments may be provided at any time about these procedures to OCAS at ocas@cdc.gov. Any subsequent revision of the procedures will be posted on the NIOSH

web site at www.cdc.gov/niosh/ocas. If there are any substantial revisions to these procedures, NIOSH will publish a Federal Register Notice including an indication that there have been substantial revisions, a paragraph summarizing the changes, and that the revised procedures can be found on the NIOSH web site at www.cdc.gov/niosh/ocas. Comments regarding these internal procedures or any revisions thereto are invited.

6.0 PROCEDURE

6.1 Determine whether the petition qualifies for evaluation

Note: The steps and procedures under 6.0 are intended to provide guidance for determining whether a petition meets the requirements specified under 42 CFR Part 83 to qualify for evaluation by NIOSH, the Advisory Board on Radiation and Worker Health ("the Board"), and the Secretary of HHS. These requirements, specified under §§83.7 and 83.9, are separate and distinct from the criteria by which the Secretary of HHS will determine whether or not to add a class of employees to the Cohort.

6.1.1 Receive, acknowledge receipt and assign the petition.

6.1.1.1 Date-stamp the petition the day it is received by NIOSH (except for electronic submissions) and log it into NOCTS by completing all the relevant fields.

6.1.1.2 Send acknowledgment of the receipt of the petition to the petitioner(s).

6.1.1.3 Assign the petition to a primary reviewer. To address concerns about a possible perceived or actual conflict of interest, OCAS or its contractor shall assign a reviewer who has never been employed -- either as a direct employee or as a contractor or subcontractor -- at the facility identified by the petition.

6.1.2 Establish the qualifications of the petitioner(s)

6.1.2.1 For petitions covered under § 83.14, verify that the petitioner identified is a claimant for a dose reconstruction that NIOSH found it could not complete.

6.1.2.2 For petitions (not covered under § 83.14) by employees and/or their survivors, or by individuals or entities they have authorized to petition on behalf of the class, verify through NIOSH records, that the employee or survivor is a DOE employee, DOE contractor employee, or AWE

employee (or survivor). If NIOSH records are insufficient for making this determination, submit a request for assistance to DOL, to inform NIOSH, based on DOL's existing EEOICPA records or through the employment verification process it uses for EEOICPA claims, whether DOL believes the employee or survivor is a DOE employee, DOE contractor employee, or AWE employee (or survivor). The employee must also have employment within the parameters of the class of employees at the DOE facility or AWE facility defined in the petition. Request verification assistance from DOL. To the extent possible, NIOSH will work with the petitioners to resolve verification problems. Petitioners and/or others may provide affidavits or other relevant evidence in cases in which records available to NIOSH are insufficient to verify that the employee (or survivor) is qualified to petition for the class of employees defined in the petition. In cases in which affidavits or other relevant evidence are used for verification, review the affidavits or other relevant evidence for their adequacy and credibility and consult the Health Science Administrator of OCAS before making a decision. NIOSH will make the final decision regarding the qualifications under this step.

6.1.2.3 For petitions by one or more labor organizations, verify that the petition includes documentation that the labor organization represents or represented one or more members of the class of employees at a DOE facility or AWE facility, as defined by the petition. Documentation would typically be a signed contract between the labor organization and the employer which specifies that the labor organization is or was an authorized bargaining unit representing one or more of the employees in the class. For employees who are or were members of labor unions that never had a contract with the employer, documentation to be provided by the labor organization could be proof of the union membership of one or more members of the class. Work with the petitioner(s) to obtain such documentation if it has been omitted.

6.1.2.4 For petitions for which the qualification of no members can be verified, notify the Health Science Administrator of OCAS by email. This email should include a complete summary of actions taken to verify the qualifications of the petitioner(s) and the results of these actions. Cease work on the petition until further notice.

6.1.2.5 For petitions for which the qualifications of at least one petitioner cannot be verified, notify the Health Science Administrator of OCAS by email. This email should include a complete summary of actions taken to verify

the qualifications of the petitioner(s) and the results of these actions. If a qualified petitioner(s) remains, continue work on the petition but treat the unqualified petitioner(s) as interested members of the public, not as petitioners, until further notice.

6.1.3 Confirm the scope of the class of employees intended by the petitioner(s) for petitions not covered under § 83.14.

6.1.3.1 Evaluate the definition of the class of employees included in the petition to ensure that the class is limited to employees that worked at a single DOE or AWE facility, as defined under 42 U.S.C. §§ 7384l(5) and (12). A facility could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing multiple buildings or structures, including the grounds upon which it is located. A petition cannot cover employees from more than one facility. If necessary, counsel the petitioner(s) to submit additional petitions such that each petition is specific to a class of employees at a single facility.

6.1.3.2 Review the class definition to ensure that it represents a class of employees that worked at a DOE or AWE facility, versus an individual employee. As required under EEOICPA and defined by 42 CFR § 83.5(c), a "class of employees" for purposes of additions to the Cohort must be a "group of employees" rather than a single individual. Furthermore, as specified under 42 CFR § 83.1, the Special Exposure Cohort procedures are not intended to provide a second opportunity to qualify a claim for compensation, once NIOSH has completed the dose reconstruction and DOL has determined that the cancer subject to the claim was not "at least as likely as not" caused by the estimated radiation doses. DOL has established procedures separate from Cohort petitions for cancer claimants who want to contest the factual findings upon which NIOSH based its dose reconstruction or the application of the NIOSH dose reconstruction methodology to those facts. A petition on behalf of an individual employee does not meet the requirements of 42 CFR § 83.9 (c).

6.1.3.3 Review the class definition to identify the applicable time period(s), locations, processes, job titles, exposure incidents and other specific parameters included by the petitioner(s). If time periods and other required parameters are not specified, or if some parameters are broader than might be expected in light of the petition justification, consult the petitioner(s) to remedy any deficiencies and to confirm that the definition is as specific as intended or possible. If the petitioner(s)

changes the class definition to remedy any deficiencies or to provide greater specificity, NIOSH or ORAU should provide the petitioner(s) with written documentation of changes in an e-mail, fax or a letter that is added to the record. The petitioner(s) should be given 10 days to respond if they have any changes to what is in the e-mail, fax, or letter. If the class definition is deficient in terms of required parameters and the petitioner(s) cannot remedy such deficiencies, notify the Health Science Administrator of OCAS.

6.1.3.4 If the petition is based on circumstances related to an exposure incident, confirm the occurrence of the exposure incident through records or information from NIOSH, DOE, an AWE, or other sources. If its occurrence cannot be confirmed by any of these sources, request confirmation from the petitioner(s), as provided for under § 83.9(c)(3). Such requests should first be made orally with explanation, but should be followed-up with a written letter summarizing the discussion and documenting the request. Responses to such requests should be provided to the Health Science Administrator of OCAS. The lack of a response to such requests within 30 days should be followed-up with a documented call to the petitioner(s) to determine the cause for delay and to provide guidance, as appropriate. The lack of a response within a subsequent 15 days, unless NIOSH had previously granted a request from the petitioner(s) for an extension of time, should be followed-up with a documented call to the petitioner(s). If, on the basis of the call, verification from the petitioner(s) is not available or forthcoming, notify the Health Science Administrator of OCAS.

6.1.3.5 For petitions based on circumstances related to a confirmed exposure incident, establish parameters defining the class of employees potentially exposed with as much specificity as can be substantiated by the information currently held by NIOSH.

6.1.4 Determine whether NIOSH is in receipt of other petitions on behalf of the same class of employees and take appropriate actions accordingly, as provided for under § 83.12(b).

6.1.4.1 If another petition under consideration completely covers the class defined in the new petition and NIOSH has not published a Federal Register notice under §83.15(a) with respect to the petition under consideration, then combine the petitions for the purposes of all steps in these procedures, providing that the new petition is determined to be qualified for evaluation. If, under these circumstances, another petition only partially covers the class defined in the new petition, then combine

the petitions for the purposes of all steps in these procedures for the overlapping class only. The class members proposed by the new petition but not covered by the petition under consideration should be handled as a separate class for the purposes of all steps in these procedures.

6.1.4.2 If another petition under consideration completely covers the class defined in the new petition and NIOSH has already published a Federal Register notice under § 83.15(a) with respect to the petition under consideration, then notify the Health Science Administrator of OCAS. A determination will have to be made as to whether the new petition presents new information. If the new petition presents such new information, then it would be further considered as a new petition, following the steps in these procedures, providing that the new petition is determined to be qualified for evaluation. If the new petition does not present such new information, then it does not satisfy the requirement under § 83.9(c)(5). Go to step 6.1.6.

6.1.4.3 If another petition under consideration partially covers the class defined in the new petition, and NIOSH has already published a Federal Register notice under § 83.15(a) with respect to the petition under consideration, then notify the Health Science Administrator of OCAS. A determination will have to be made as to whether the new petition presents new information with respect to the class covered by both petitions. If so, then it would be further considered in its entirety as a new petition, following the steps in these procedures, providing that the new petition is determined to be qualified for evaluation under § 83.9. If not, then the petition would be further considered with respect to the part of the class defined in the new petition that is not covered by the petition already under consideration. These class members should be handled as a separate class for the purposes of all steps in these procedures, providing that the new petition is determined to be qualified for evaluation under § 83.9. For the part of the class for which the new petition does not present new information as required under § 83.9(c)(5), go to step 6.1.6

6.1.4.4 If HHS has already made its decisions with respect to the designation of a class covered in part or in its entirety by the new petition, then notify the petitioner(s) of these decisions. If the petition covers class members who have not been designated for addition to the Cohort, then notify the Health Science Administrator of OCAS. As appropriate, as described under 6.1.4.2 and 6.1.4.3, determine whether the new petition provides new information with respect to the class or part of the class, and proceed accordingly to consider the petition and/or to step 6.1.6.

6.1.5 For petitions not covered under § 83.14, review the petitioner's basis for believing records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class with sufficient accuracy.

6.1.5.1 Evaluate the basis for the petition provided by the petitioner(s) to determine whether it complies with the requirements of § 83.9(c)(2) and (3).

6.1.5.1.1 Under paragraphs (i) and (ii) of § 83.9(c)(2) and paragraphs (ii) and (iii) of § 83.9(c)(3), affidavits must be sufficiently specific and factual to indicate the assertion in the affidavit(s) is based on the experience of employees who are members of the class covered by the petition or other witnesses, as appropriate. In addition: (1) consider the applicability of assertions to the circumstances of the petitioning class of employees when such assertions are based on circumstances among classes of employees at the facility who might reasonably be considered to be separate from the petitioning class of employees; examples of such classes are employees that worked during a different time period, under different management, or under different exposure, monitoring, or recordkeeping procedures; and (2) consider the adequacy and credibility of assertions in consultation with the Health Science Administrator of OCAS; in some cases, it may be useful to involve persons with a variety of perspectives to thoroughly consider concerns about the adequacy and credibility of an assertion.

Discussion: "Adequacy" and "credibility" are not judgments subject to any rigid criteria; because each case is likely to be unique, "adequacy" and "credibility" will be determined on a case-by-case basis, based on a totality of the circumstances.

6.1.5.1.2 Under paragraph (i) of § 83.9(c)(2), if the documentation provided by the petitioner consists solely of communications from DOE or an AWE to the petitioner indicating that it lacks monitoring records on any members of the proposed class, then attempt to determine whether NIOSH has access to records on the class members. Make such a determination within 30 days. If the records are available to NIOSH, notify the petitioner that NIOSH has access to the information it needs to begin a dose reconstruction. If the petitioner still seeks to petition, the

petitioner will be required to provide another basis to satisfy the requirements of this section.

6.1.5.1.3 Under paragraph (iv) of § 83.9(c)(2), note that the scientific or technical report can be from the Government Accounting Office, the Defense Nuclear Facilities Safety Board, the Nuclear Regulatory Commission, or from any level of the Executive Branch of government, including federal, state, and local executive agencies. It is possible, for example, that a state environmental or public health agency might have examined the availability of dosimetry and related information with respect to an AWE.

6.1.6 Notify petitioners in writing of petitions that do not satisfy all relevant requirements under §§ 83.7 - 83.9.

6.1.6.1 Upon request by the Health Science Administrator of OCAS, prepare for his/her signature a letter to the petitioner(s) that notifies the petitioner(s) of any requirements that are not met by the petition, providing a summary of prior discussions with the petitioner(s) concerning such deficiencies, and providing guidance on how such deficiencies could be remedied, if possible. The letter should notify the petitioner(s) of a 30-day time limit to remedy the deficiencies identified, or of a specific extended period, when an extension has been granted. Use standard format and prepared text inserts. The Health Science Administrator of OCAS (or a delegate) is solely authorized to issue such notification.

6.1.6.2 Provide further oral or written guidance to the petitioner(s) upon request and to a reasonable extent. Document all oral and written communications with the petitioner(s) with appropriate annotation to the administrative record (both hard copy file and in NOCTS). Any oral guidance provided to the petitioner addressing substantive issues must also be documented in a follow-up letter to the petitioner.

6.1.7 Notify the Health Science Administrator of OCAS of petitions that remain unsatisfactory after 30 calendar days or an extended period, if granted, from the date of notification to the petitioner(s) under 6.1.6, reporting any oral or written communications that have occurred during this period.

6.1.8 The Director of OCAS will establish and notify the petitioner(s) of proposed findings that a petition fails to meet the specified requirements and the basis for this finding. The Director is solely authorized to issue such notification, which

must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s).

6.1.9 Proposed findings that a petition fails to meet the specified requirements are subject to administrative review, as specified under §§ 83.11. Upon the written request of the petitioner(s) pursuant to § 83.11(c), the Director of NIOSH will appoint three HHS personnel to conduct a review. Such personnel will not have ever been employed at the DOE site in question or by DOE headquarters offices responsible for the DOE site in question, nor will they have ever been employed by OCAS.

6.1.9.1 If a review is conducted, upon the appointment of reviewers, provide to the reviewers the administrative record associated with the petition, including the petition request, the petition review, related records, materials and communications, and the request by the petitioner(s) for a review of the proposed finding.

6.1.9.2 Upon the completion of a NIOSH review, the Director of NIOSH will directly transmit to the petitioner(s) a report on the review and its outcome, which must be reviewed by OGC prior to being sent to the petitioner(s). Enter the report and associated transmittal communications into the administrative record for the petition.

6.1.10 If no request for an administrative review is received from the petitioner(s) within 31 days of notification of a proposed finding that a petition fails to meet specified requirements, the proposed finding becomes a final decision. Provide to the Health Science Administrator for the signature of the Director of OCAS a draft notice to the petitioners documenting that the petitioners did not request a review and that the proposed finding represents a final decision. This notice must be reviewed by OGC prior to being sent to the petitioner(s). A signed copy of the final notice shall be entered into the administrative record.

6.1.11 For any petition for which the petitioner(s) had to revise the petition before it could qualify for evaluation, date the petition in the NOCTS tracking system as being submitted on the day on which the revised petition was submitted to NIOSH.

6.2 Provide notification of a petition that has been selected for evaluation.

Note: The steps and procedures under 6.2 provide guidance for issuing appropriate notification to petitioners, the Board, and the public that a petition will be evaluated by NIOSH, the Board, and HHS because it meets the requirements of Step 6.1.

6.2.1. Provide written notification to the petitioner(s) that their petition will be evaluated. Notification should include the appropriate standard notification letter and the SEC Evaluation Process Summary (Appendix A).

6.2.2. The Director of OCAS or his/her designee will issue the notification to the petitioners.

6.2.3. Prepare and submit to the Health Science Administrator a notification package for the Board, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to Board. The evaluation package should include the following: (A) the petition or petitions (multiple petitions may have been received representing a single class of employees); (B) an evaluation plan for the class addressed in the petition(s), including the following, as required under § 83.12(b) and (c): (1) an initial proposed definition for the class of employees based on the petition, when applicable, and on NIOSH information that would establish a definition (for petitions submitted under § 83.14) or modify the definition proposed by the petitioner(s); (2) a list of activities for evaluating the radiation exposure potential of the class of employees and the adequacy of existing records and information to support dose reconstructions for members of the class of employees.

6.2.4. OCAS will prepare a monthly Federal Register notice (when necessary) notifying the public of the decision(s) to evaluate petitions.

6.2.5. Upon publication of the Federal Register notice, OCAS will post the notice to the OCAS Web page. OCAS may also disseminate the notice through direct and media contacts

6.3. Evaluate a petition qualifying for evaluation under §83.13.

Note: The steps and procedures under 6.3 provide guidance for OCAS to conduct its evaluation of a petition when the petition is <u>not</u> by a claimant for whom NIOSH has already found that it cannot complete a dose reconstruction. The guidance attempts to balance the goal of NIOSH to address the issues raised by petitioners thoroughly, whenever possible, with the importance of completing petition evaluations in a timely manner. For this purpose, the guidance limits activities for collecting records and information from sources outside of NIOSH, whenever possible, and limits the scope of evaluations to address the particular issues and facts raised by petitions.

6.3.1. Procedures for determining feasibility: (1) The principal guidelines for evaluating feasibility for petitions qualifying for evaluation under 6.3 are established under § 83.13(c)(1). (2) The technical issues involved in evaluating the availability and adequacy of records and information relevant to feasibility determinations are

addressed in the implementation guidelines for internal and external dose reconstructions. These dose reconstruction guidelines generally explain the types of information that can be used in dose reconstructions, and approaches to examine the availability and adequacy of information, as well as describing how such information should be used. These guidelines also provide general guidance concerning how maximum doses can be estimated when necessary, and the information essential to such estimates, under section 5.3 of the internal dose reconstruction guidelines and sections 3.1.3, 3.1.4, 3.2.3, 3.3.3, and 3.3.4 of the external dose reconstruction guidelines. The efficiency measures in the internal dose reconstruction guidelines (e.g., high dose potential and low dose potential preliminary estimates), however, are not applicable to evaluating feasibility with respect to a class of employees. (3) Subject to § 83.13(c)(1) and the procedures provided under 6.3.6 and 6.3.7 below addressing timeliness, feasibility should be determined by evaluating the availability and adequacy of records and information in the order established by the hierarchy of dose reconstruction information specified under 42 CFR § 82.2, addressing the informational sources, types, and the adequacy of information as specified under 42 CFR Part 82 and 83 and under the OCAS implementation guidelines for dose reconstruction. Site profiles, for sites for which they have been issued, will provide an important resource of information to assist in evaluating feasibility (recognizing, however, that petitions may raise issues not yet identified through the site profile development process). (4) Positive determinations of feasibility under steps 6.3.1 and 6.3.3 – 6.3.6 must be applicable to dose reconstruction for *any* type of cancer, otherwise dose reconstruction must be deemed not feasible for the class of employees.

6.3.2. Procedures for determining the extent and specificity of evaluations supporting positive determinations: Positive determinations of feasibility under steps 6.3.1 and 6.3.4-6.3.6 are not required to be supported by evaluations that are more extensive or more specific in scope than the information provided by the petitioner(s) under 42 CFR § 83.9(c)(2) to support the belief of the petitioner(s) concerning the feasibility of dose reconstruction. A petition based on alleged informational deficiencies relating to a group of employees at a facility can be addressed by determining the availability and adequacy of such information for the group as a whole, without examining all potentially different subgroups or individuals thereof. A petition submitted on the basis of alleged informational deficiencies relating to particular individuals can be addressed by determining the availability and adequacy of information germane to dose reconstruction for those particular individuals.

Example 1: The petition asserts that personnel monitoring was not conducted for a group of maintenance workers when they were engaged in a particular operation.

An examination of records shows that the maintenance workers were not monitored while engaged in the particular operation but that another group of maintenance workers were monitored while engaged in the same operation involving comparable exposure conditions at another location at the facility.

This information might be sufficient to determine that dose reconstruction is feasible for the group of maintenance workers covered by the petition, while engaged in the particular operation. It would not be necessary to evaluate the availability and adequacy of records concerning the work of the group of maintenance workers while engaged in other operations not addressed by the petition.

Example 2: The petition asserts on the basis of the records of specific individual employees that personnel monitoring records are not available for employees who worked at facility "S" from 1943 – 1946. On this evidence, the petitioners believe dose reconstruction is not feasible for employees at the facility during this time period.

An examination of records shows that the personnel monitoring program in place at facility "S" at that time relied on a co-worker approach to monitoring, such that not all workers who could have been monitored were monitored. The records also indicate that the individual cases identified are consistent with the co-worker monitoring practice employed at the time.

This information might be sufficient to determine dose reconstruction is generally feasible for employees who worked at facility "S" during this time period. It is not necessary to examine whether this finding is applicable to every employee who worked at the facility during the specified time period. In this case, the evaluation need only examine the circumstances of individuals for which the petitioners provided information specifically supporting their belief that dose reconstruction may not be feasible.

Example 3: The petition asserts that employees who worked at facility "B" were not monitored during a particular operation that occurred in 1955. On this evidence, the petitioner believes that dose reconstruction is not feasible for employees who worked in the operation.

An examination of records shows that NIOSH has completed dose reconstructions without personnel monitoring data to estimate the radiation doses of employees who worked in the operation.

This information might be sufficient to determine that dose reconstruction is generally feasible for employees who worked in the operation. It is not necessary for NIOSH to examine whether this finding is applicable to any possible subgroups of employees who worked in the operation, as the information provided in the petition did not suggest feasibility issues associated with any specific subgroup of employees.

6.3.3. Determine whether one or more dose reconstructions have been completed and/or initiated that demonstrate that dose reconstructions are feasible for the class of employees identified in the petition, or, if appropriate under 6.3.2, for a subgroup thereof, in light of the information provided in the petition concerning the feasibility of estimating radiation doses for the class of employees identified in the petition. When such dose reconstructions are identified, prior to proceeding from this step, consult the Health Science Administrator to determine whether any such dose reconstructions are presently being considered by DOL's Final Adjudication Branch (FAB) pursuant to an objection by a claimant under 20 C.F. R. § 30.318 in response to a recommended decision by DOL to deny the claim. If so, suspend work until the final decision of the FAB is issued pursuant to 20 C.F.R. § 316(d).

6.3.3.1. If one or more dose reconstructions have been completed or initiated and they demonstrate feasibility for the petitioning class of employees, go to step 6.3.9.

6.3.3.2. If one or more dose reconstructions have been completed or initiated and they demonstrate feasibility only for a subgroup of the petitioning class of employees, as appropriate under 6.3.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which feasibility must still be determined). Go to step 6.3.9 for the class for which dose reconstruction is feasible and go to step 6.3.4 for the class for which the feasibility of dose reconstruction must still be determined.

6.3.3.3. If dose reconstructions that have been completed or initiated do not demonstrate feasibility for any subgroup of the petitioning class of employees, go to step 6.3.4.

Example: The petition asserts on the basis of affidavits that employees who worked at facility "B", a single building, were not monitored during two phases of a specified operation that occurred in 1955. On this evidence, the petitioner believes that dose reconstruction is not feasible for employees who worked in the operation.

An examination of records shows that NIOSH has completed dose reconstructions in which NIOSH used area monitoring data, without personnel monitoring data, to estimate the radiation doses of employees who worked in the specified operation at facility "B." The examination confirms, however, that there were two distinct phases of the operation, "1" and "2," finds that exposures and record availability might differ substantially

between these two phases, and documents that NIOSH dose reconstructions have only addressed "phase 1."

This information might be sufficient to determine dose reconstruction is generally feasible for employees who worked in "phase 1" of the operation at facility "B." It is not necessary for NIOSH to examine whether this finding is applicable to specific subgroups of employees who worked in "phase 1" of the operation, as distinctions concerning subgroups were not addressed by the evidence provided in the petition. This information is not sufficient to evaluate the feasibility of dose reconstruction for employees who worked in "phase 2." The feasibility of dose reconstruction for employees who worked in "phase 2" should be evaluated further, treating these employees as a class distinct and apart from employees who worked in phase 1.

6.3.4. If current and/or completed dose reconstructions do not fully address the information provided by a petition, then determine whether personnel and/or area monitoring data are available and adequate to conduct dose reconstructions for members of the petitioning class of employees or, if appropriate under 6.3.2, for a subgroup thereof.

6.3.4.1. If the personnel and/or area monitoring data are available and adequate to conduct dose reconstructions for the class of employees considered in this step, go to step 6.3.9.

6.3.4.2. If the personnel and/or area monitoring data are available and adequate to conduct dose reconstructions only for a subgroup of the class of employees considered in this step, as appropriate under 6.3.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which it is not). Go to step 6.3.9 for the class for which dose reconstruction is feasible and go to step 6.3.5 for the class for which personnel and/or area monitoring data are not available and adequate.

6.3.4.3. If personnel and/or area monitoring data are not available and adequate to conduct dose reconstructions for any subgroup of the class of employees considered in this step, go to step 6.3.5.

6.3.5. If, under step 6.3.4, personnel and/or area monitoring data are not available and adequate to conduct dose reconstructions for members of the petitioning class of employees or a subgroup thereof, then determine whether the radiation source term, source, and process information are available and adequate to conduct dose reconstructions without monitoring data or in combination with any monitoring data available.

6.3.5.1. If the radiation source term, source, or process information are available and adequate to conduct dose reconstructions without monitoring data or in combination with any monitoring data available, go to step 6.3.9.

6.3.5.2. If the radiation source term, source, or process information are available and adequate to conduct dose reconstructions only for a subgroup of the class of employees considered in this step, as appropriate under 6.3.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which it is not). Go to step 6.3.9 for the class for which dose reconstruction is feasible and go to step 6.3.11 for the class for which dose reconstruction is not feasible.

6.3.5.3. If available radiation source term, source, and process information are not adequate to conduct dose reconstructions for any subgroup of the class of employees considered in this step without monitoring data or in combination with any monitoring data available, go to step 6.3.11.

6.3.5.3.1. If there is no monitoring, source, source term, or process information from the site where the employee worked to serve as the basis for a dose reconstruction, then a dose reconstruction is not feasible; go to step 6.3.11. EEOICPA (42 U.S.C. § 7384n(c)(3)(A)) requires that probability of causation determinations be based on information from the site where the employee worked. Such information must, at a minimum, include some monitoring, source, source term, or process information from the site where the employee worked, rather than from a comparable site. This requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but the dose reconstruction must have, as a basis, some information from the site where the employee worked.

6.3.6. Timeliness Procedures: To achieve timeliness in conducting steps 6.3.4 and 6.3.5: (a) Research records and data in NIOSH's possession should be evaluated and used, if sufficient, without requesting additional records from DOE, an AWE, or other resources; (b) When records or information from DOE, an AWE, or another resource are necessary, request simultaneously the records or information for steps 6.3.4 and 6.3.5; (c) Minimize the scope and extent of records requests to support a timely evaluation (see procedures under 6.3.8); (d) If records or information requested under (b) above are not provided within 60 days, or if a

resource indicates such records cannot be provided within 120 days, notify the OCAS Health Science Administrator.

6.3.7. Timeliness Policy: Under § 83.13(b), the Director of OCAS may determine that records and/or information requested from DOE, an AWE, or another resource to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.

6.3.7.1. Before the Director of OCAS makes such a determination, the resource(s) potentially in possession of such records and/or information will be allowed a reasonable amount of time, as determined by the Director of OCAS, to provide the records and/or information.

6.3.7.2. Such a determination may take into account the types and quantity of records and/or information requested from the resource, as well as any other factors that might be relevant to the judgment under paragraph (1) of the amount of time that is reasonable to provide the records and/or information, which would be decided on a case-by-case basis by the Director of OCAS.

6.3.8. Guideline for Requesting Records and information from DOE, an AWE, and Other Resources: NIOSH should only request such records and information from resources external to NIOSH that are necessary to make feasibility determinations with respect to the class and, when necessary, to evaluate issues of health endangerment with respect to the class. The purpose of requesting records is *not* to obtain all the records that might be required to actually conduct dose reconstructions for members of the class of employees. For example, it may only be necessary to obtain a sample of personnel and/or area monitoring records pertaining to the class to evaluate the feasibility of dose reconstruction. Appendix B includes a standard records request form to be submitted to DOE when necessary. This form provides a template for requesting information from other resources as well.

Note 1: The purpose of requesting personnel records, when necessary, is to obtain reasonable evidence to evaluate more general information provided by the resource to determine whether dose reconstruction is feasible. Do not request a larger sample of records than is necessary, since this can affect the timeliness of the response.

Note 2: In cases in which the evaluation has already determined the feasibility of dose reconstruction but the petition raised issues that have not been fully addressed, achieving a reasonable balance between comprehensiveness and timeliness is important. If

conducting a comprehensive evaluation would delay the completion of the petition evaluation substantially (e.g., by more than 60 days), consult with the Health Science Administrator. It may be appropriate to complete the petition evaluation sooner, based on minimally sufficient information, and to complete the evaluation of monitoring practices separately.

6.3.9. For classes of employees for which dose reconstruction is feasible, prepare a finding explaining the basis for the determination.

6.3.9.1. Describe the approach or approaches to dose reconstruction that are feasible for members of the class of employees.

6.3.9.2. Procedures for explaining feasibility when dose reconstruction is feasible: (1) Address directly the rationale and information provided by the petitioner(s) to support the petition. Explain whether the rationale and information are accurate and relevant and explain why they are not an impediment to dose reconstruction. (2) Identify the types and limitations of data that are available for dose reconstruction and include an explanation of methods that could be used to conduct dose reconstructions using these types of data and accounting for the limitations specified. (3) Reference relevant sections of the OCAS dose reconstruction implementation guidelines and other relevant documents that relate to the approach or approaches that could be used for the dose reconstructions discussed. (4) Explain that the methods used for actual dose reconstructions for members of the class of employees may differ from the methods discussed, based on the work history, cancer, and other characteristics of the individual employee whose doses are being reconstructed and based on the records available at the time the dose reconstruction is conducted.

6.3.10. For classes of employees for which dose reconstruction is not feasible, prepare a finding explaining the basis of the determination.

6.3.10.1 Describe the informational limitations established by the NIOSH evaluation and explain why these limitations make it not feasible for NIOSH to complete dose reconstructions for the class of employees.

6.3.10.2 Procedures for explaining feasibility when dose reconstruction is not feasible:(1) Identify the information that, at minimum, must be available to reconstruct the doses of members of the class of employees and summarize how such information would be used in dose reconstructions. (2) Summarize the actions taken to obtain sufficient information for dose reconstruction. (3) Identify the information that NIOSH obtained and

the necessary information that NIOSH was unable to obtain and document how it was determined that necessary information is not available. (4) Individuals included in the Cohort might require a dose reconstruction, if they were to incur a cancer not included among the 22 specified cancers covered by EEOICPA for members of the Cohort. In circumstances in which NIOSH might have sufficient information to reconstruct the radiation doses of members of the class with particular cancers not included among the 22 specified cancers, identify such circumstances and the cancer or cancers to which they relate. (5) Include the following statement: "The determination by NIOSH that it cannot estimate radiation doses with sufficient accuracy for members of this class does NOT necessarily mean that NIOSH cannot estimate ANY radiation doses with sufficient accuracy for ALL members of this class. In a case in which a member of this class incurred a cancer not included among the 22 specified cancers covered by EEOICPA and hence requires a dose reconstruction (or would otherwise be left without a remedy), it is possible that NIOSH could reconstruct some or all of the radiation doses relevant to the individual's cancer in conformance with 42 CFR Part 82.

6.3.11. For classes of employees for which dose reconstruction is not feasible, evaluate health endangerment by examining whether the class of employees was exposed during a discrete incident likely to have involved exceptionally high level radiation exposures, comparable to the levels of exposure in nuclear criticality incidents.

6.3.11.1. Characterize the source(s) and circumstances of radiation exposure to the class of employees.

6.3.11.2. Establish whether the sources and circumstances indicate that the class of employees was likely to have received exceptionally high level radiation exposures. The analysis should use comparative information when feasible, considering comparable exposure incidents in which radiation levels or related health effects were documented. Determinations should find the occurrence of exceptionally high level radiation exposures to be either "likely" or "unlikely."

6.3.11.3. Establish the duration of "discrete incidents." It is possible to define a discrete incident as having any duration. However, an incident of long duration (e.g., months) would be extraordinary. Exceptionally high levels of radiation exposure, as defined, typically have resulted from a recognized breakdown of radiological controls and such levels of exposure typically cause acute, radiation-related health effects.

6.3.12. Define the class or classes of employees evaluated in response to the petition.

6.3.12.1. Define separate classes of employees for each separate determination of feasibility resulting from the evaluation of the petition. For example, if the petition evaluation were to find that it is feasible to conduct dose reconstructions for one group of employees using monitoring data and a second group using source term and process data, and that it is not feasible to conduct dose reconstructions for a third group of employees, then define three classes of employees.

6.3.12.2. Define the class of employees as completely and precisely as possible. The definitions are important to potential petitioners, who need to be able to recognize whether or not they are included in the class. The definitions are also important to DOL, which will make compensation decisions on the basis of class definitions for classes of employees that are added to the Cohort. The definition should provide information sufficient to clearly distinguish between employees who are included and omitted from the class. In addition to addressing the employment parameters defined under § 83.13(c)(2), consider whether it is necessary to specify work operations, employers (e.g., contractor, subcontractor), work schedule, and any other characteristics that help precisely define the membership of the class of employees. Also, note that a class should always be defined by generic employment parameters as described above; it may not name individuals and it must potentially include more than one individual.

6.3.12.2.1. The Health Science Administrator will consult with DOL to determine whether the class definition is specified by parameters that will allow DOL to determine whether a claimant is or is not a member of the class. In some cases, it is possible that NIOSH would be able to define a class of employees by parameters more precise than those DOL would be able to apply in making such determinations. In such cases, NIOSH should consider whether to limit the class definition to the parameters of utility to DOL and the feasibility determination under step 6.3.10.2 could separately define the more specific class parameters upon which the determination is based.

6.3.12.3. For each class of employees for which dose reconstruction is not feasible, indicate within the class definition whether the minimum 250

work days employment requirement for health endangerment applies to the class of employees, based on the analysis under step 6.3.11.

6.3.12.4. For each class of employees for which the 250 work days employment requirement for health endangerment applies, include prepared text specifying that for the purpose of determining whether an employee in the class meets the 250 work days employment requirement, the class definition includes any of the employee's work days accrued while employed in another class of employees in the Cohort (notwithstanding any duration of employment requirements applicable to membership in such other classes).

6.4. Evaluate the petition qualifying for evaluation under § 83.14, for a claimant for whom OCAS was unable to complete a dose reconstruction.

Note: The steps and procedures under 6.4 provide guidance for OCAS to evaluate a petition by a claimant for whom OCAS found it was unable to complete a dose reconstruction. In these situations, as provided for by § 83.14, the determination that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy is already established. This guidance concerns the remaining steps of defining the class of employees, addressing health endangerment, and determining whether there may be a more extensive class of employees that requires further evaluation and consideration for addition to the Cohort as a separate class of employees.

6.4.1. Define the class of employees for whom dose reconstruction is not feasible.

6.4.1.1. Review the information obtained by OCAS and the rationale justifying the OCAS finding that a dose reconstruction could not be completed for the employee identified in the petition.

6.4.1.2. Define the class of employees for which the information under 6.4.1.1 applies, using the procedures under 6.3.12. As noted under step 6.3.12.2, a class should always be defined by generic employment parameters; it may not name individuals and it must potentially include more than one individual.

6.4.2. Evaluate the likelihood of exceptionally high radiation exposure to the class of employees defined under step 6.4.1. Use the procedure under step 6.3.11.

6.4.3. Based on the evaluation under step 6.4.2 and the definition under step 6.4.1, define a class of employees for which it can be determined that: (1) it is not

feasible to estimate the radiation doses of individual members of the class of employees with sufficient accuracy; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class of employees. For the class of employees defined under this step, go to step 6.5 to prepare a report of the evaluation findings.

6.4.4. Determine whether the existing information under 6.3.1.1 indicates the potential for another class of employees for which dose reconstruction might not be feasible, beyond the scope of the group defined under step 6.3.1.2. If such a potential exists, initiate an evaluation under 6.2.

Example: OCAS found it could not complete a dose reconstruction for employee John Q. Public. Mr. Public was exposed to radiation during an incident, for which there are no monitoring data and inadequate source term and process data. Under step 6.4.1.2, all workers employed in the immediate area of the incident or in responding to the incident were included in the group. However, the records reviewed during the attempted dose reconstruction for Mr. Public were not sufficient to determine whether workers were employed in areas proximate to the incident and might have been similarly exposed. This possibility will need further investigation.

6.5. Prepare an evaluation report responding to the petition(s).

Note: The steps and procedures under 6.5 provide guidance for OCAS to prepare a report of its evaluation findings.

6.5.1. For petitions for classes that qualified under § 83.13, prepare an evaluation report according to the requirements of § 83.13(d). Use the appropriate OCAS template for this report from Appendix C.

6.5.2. For petitions qualified under § 83.14, prepare an evaluation report according to the requirements of § 83.13(d)(1)-(3) and (5) and § 83.14(b). The report must also provide notification of whether a determination has been made under step 6.4.4 that the existing information under step 6.4.1.1 indicates the potential for another class of employees for which dose reconstruction might not be feasible, extending beyond the scope of the group defined under step 6.4.1.2. If such a potential exists, explain that an evaluation under step 6.3 will be conducted, and explain the basis for this decision. Use the appropriate OCAS template for this report, from Appendix C, and assure that appropriate redactions have been made to protect the privacy of individuals.

6.5.3. The Director of OCAS must approve the petition evaluation report, and OGC must review it for privacy and other legal considerations, before it can be transmitted to the Board under step 6.6.

6.6. Transmit and publicize the evaluation report

Note: The steps under 6.6 provide guidance for OCAS to transmit its evaluation findings to petitioners, the Board, and the public.

6.6.1. Transmit the approved evaluation report to the petitioner(s) and members of the Board as soon as possible after approval.

6.6.2. Prepare an entry for the Federal Register notice of the next Board meeting summarizing the petition and the findings of the NIOSH evaluation report. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.6.3. Post the Federal Register notice on the OCAS Web Page as soon as possible after approval.

6.7. Schedule a presentation to the board

Note: The procedures under 6.7 provide guidance for OCAS to schedule a presentation of the evaluation report prepared under step 6.6 to the Board.

6.7.1 OCAS will schedule the presentation to the Board of the petition and the NIOSH evaluation as soon as possible, taking into account such matters as the need for Board members to review the report prior to the meeting, the requirements of the Federal Advisory Committee Act (FACA), and the scheduling needs of the petitioner(s), if the petitioner(s) intends to attend the Board meeting.

6.7.2 It is essential to obtain the Board's review of a petition qualifying under § 83.14 as soon as possible, since these petitions involve a claim for which it is already determined that dose reconstruction is not feasible and hence adjudication of the claim by DOL relies on completion of the petition evaluation process. NIOSH will make every effort to schedule consideration of these petitions as soon as possible, consistent with step 6.7.1.

6.7.3 As provided in § 83.15(b), in considering the petition, both NIOSH and the members of the Board will take all steps necessary to prevent the disclosure of information of a personal nature, concerning the petitioners or others, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

This may include such steps as making appropriate redactions of documents and holding closed meetings of the Board under FACA.

6.8. Establish a proposed decision on the outcome of the petition(s)

Note: The steps and procedures under 6.8 provide guidance for OCAS to support the Director of NIOSH in establishing proposed decisions.

6.8.1. Proposed decisions will take into account the petition, the evaluation(s) of NIOSH and the report and recommendations of the Board, and may also take into account other information presented or submitted to the Board and the deliberations of the Board.

6.8.2. Proposed decisions must comply with the provisions of §§ 83.13(c) or 83.14(b), as appropriate.

6.8.3. A single petition may result in one or more proposed decisions to add a class of employees to the Cohort and/or to deny adding a class of employees to the Cohort. This depends on the number of separate classes of employees defined by the Director of NIOSH, based on the information identified under 6.3.12.

6.8.4. The Director of NIOSH will determine the proposed decision.

6.8.5. OCAS will prepare a report of the proposed decision, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s). The report of the proposed decision must include a detailed definition of the class of employees, an iteration of the relevant criteria, as specified under § 83.13(c), and a summary of the information and findings on which the proposed decision is based.

6.8.6. The Director of NIOSH or his/her designee must approve the report.

6.9. Transmit proposed decisions to the petitioners

Note: The steps and procedures under 6.9 provide guidance for OCAS to transmit proposed decisions established by the Director of NIOSH and to expedite final decisions when appropriate.

6.9.1. Transmit the approved report or report(s) to the petitioner(s) as soon as possible after approval. The report(s) should be accompanied by a transmittal letter that notifies the petitioner(s) of the remaining steps in the petition process, including the procedures and requirements for contesting a proposed decision and for waiving the right to contest a proposed decision (for petitioner(s) who wish to

expedite issuance of a final decision). If a petition resulted in multiple decisions and reports, the reports should be accompanied by a summary explaining the basis for distinguishing multiple classes of employees.

6.9.2. OCAS should notify HHS immediately if the petitioner(s) has waived the right to contest a proposed decision.

6.10. Conduct an HHS administrative review of proposed decisions, as necessary.

Note: Petitioner(s) may request an administrative review of a proposed decision of the NIOSH Director to not add a class of employees to the Special Exposure Cohort

6.10.1. After the Director of NIOSH completes the steps required by 6.9, HHS will provide the petitioner(s) 30 calendar days to contest a proposed decision to not add a class of employees to the Special Exposure Cohort.

6.10.1.1. Such challenges must be submitted in writing.

6.10.1.2. The challenge must include evidence that the proposed decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures of 42 CFR Part 83.

6.10.1.3. Challenges may not introduce new information or documentation concerning the petition or the NIOSH or Board evaluation(s) that was not submitted or presented by the petitioner(s) or others to NIOSH or to the Board prior to the Board's issuing its recommendations under § 83.15.

6.10.2. If the petitioner submits a proper, written appeal of the NIOSH Director's proposed decision to not add a class of employees to the Special Exposure Cohort, the Secretary (or his designee) will appoint a panel of three HHS personnel, independent of NIOSH, who were not previously involved in the review of the petition(s). The Secretary (or his designee) will appoint one member of the panel as the chair, who will be responsible for convening the panel and transmitting the panel's recommendation under step 6.10.4.

6.10.3. The appointed panel of three HHS employees will conduct an administrative review based on a challenge submitted by the petitioner(s) and provide recommendations of the panel to the Secretary (or his designee) concerning the challenge's merits and the resolution of issues contested by the challenge.

6.10.3.1. The panel shall consider whether HHS substantially complied with the procedures of 42 CFR Part 83, the factual accuracy of the information supporting the proposed decision, and the principal findings and recommendations of NIOSH and those of the Board issued under § 83.15.

6.10.3.2. The review will consider, in addition to the views and information submitted by the petitioner(s) in the challenge, the proposed decision, the NIOSH evaluation report(s), and the report containing the recommendations of the Board.

6.10.3.3. The review may also consider information presented or submitted to the Board and the deliberations of the Board prior to the issuance of the recommendations of the Board under § 83.15.

6.10.4. Upon completion of the panel's deliberations, the panel will prepare and transmit to the Secretary (or his designee) a report of the findings of the panel.

6.10.4.1. The report will be based on the majority opinion of the panel. The chair will appoint one member of the majority to write the majority opinion of the panel. The chair can appoint himself to write the majority opinion if he is in the majority.

6.10.4.1.1 The majority report will indicate whether or not the panel supports the proposed decision made by the Director of NIOSH, and the rationale for the panel's determination.

6.10.4.2. A minority addendum may be prepared by a dissenting member of the panel and added to the final report of the panel that is being submitted to the Secretary (or his designee) for consideration.

6.10.4.2.1. A minority addendum, if one is prepared, will indicate whether or not the minority supports the proposed decision made by the Director of NIOSH, and the rationale for that determination.

6.11. How the secretary (or his designee) will make and report a final decision

Note: The Secretary (or his designee) will make a final decision whether or not to add a class of employees to the Special Exposure Cohort

6.11.1. The Secretary (or his designee) will make the final decision to add or deny adding a class to the Cohort after considering information and recommendations provided

to the Secretary (or his designee) by NIOSH, the Board, and from an HHS administrative review, if such a review is conducted.

6.11.1.1. The final report will include the decision to add or deny adding a class to the Special Exposure Cohort, an iteration of the relevant criteria, as specified under § 83.13(c) for adding or denying the addition of the class, a summary of the information and findings on which the decision is based and the definition of the class.

6.11.2. HHS will transmit a report of the final decision, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC, to the petitioner(s).

6.11.3. HHS will publish a notice, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC, summarizing the final decision in the Federal Register.

6.12. Transmit and publicize final decisions

Note: The steps and procedures under 6.12 provide guidance for OCAS to transmit and publicize final decisions established by the Secretary of HHS. When the Secretary (or his designee) makes the determination to add a class of employees to the Cohort, a report must be submitted to Congress. A final decision to add a class to the Cohort by the Secretary (or his designee) will take effect 180 days after the submission of the report to Congress, unless Congress takes an action that reverses or expedites the designation.

6.12.1. Prepare a report of the final decision of the Secretary. The report of the proposed decision must include a definition of the class of employees, an iteration of the relevant criteria, as specified under § 83.13(c), and a summary of the information and findings on which the final decision is based. This report must be reviewed by OGC prior to being sent to the Secretary.

6.12.2. Reports of final decisions must be approved by the Secretary of HHS or his/her designee.

6.12.2.1. If the Secretary (or his designee) makes a final determination to not add a class of employees to the Special Exposure Cohort, there is no congressional review of that designation and it immediately becomes a final agency decision, go to step 6.12.3.

6.12.2.2. If the Secretary (or his designee) designates a class of employees to be added to the Cohort, the Secretary (or his designee) will transmit a report of the designation to Congress pursuant to § 83.17(a).

6.12.2.2.1. The report to Congress will provide the definition of the class of employees covered by the designation, and the criteria and findings upon which the designation was based. The report will be appropriately redacted to protect the privacy of individuals, and be reviewed by OGC.

6.12.2.2.2. A designation of the Secretary (or his designee) to add a class of employees to the Cohort will take effect 180 calendar days after the date on which the report of the Secretary (or his designee) is submitted to Congress, unless Congress takes an action that reverses or expedites the effect of the designation.

6.12.3. Transmit the approved report to the petitioner(s) pursuant to § 83.16(d). This report must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s).

6.12.3.1. If the report is for the addition of a class of employees, it must clearly indicate that the designation of additional class members is not final until after the expiration of the 180 day congressional review period or when Congress takes an action that reverses or expedites the designation, which ever comes first.

6.12.3.2. The report should indicate that a final report, inclusive of congressional action, will be issued at the end of the 180 day congressional review period or after Congress takes an action that reverses or expedites the designation, which ever comes first.

6.12.4. Post the redacted and OGC-cleared report on the OCAS Web Page.

6.12.5. Prepare and publish a Federal Register notice summarizing the final decision. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.13. Transmit and publicize the outcome of congressional review

Note: The steps and procedures under 6.11 provide guidance for OCAS to transmit and publicize the outcome of final decision established by the Secretary of HHS to add a class of employees to the Cohort, following the opportunity for Congress to review the decision.

6.13.1. Prepare a report of the outcome of the HHS decision to add a class to the Cohort. The report must include a detailed definition of the class of employees, the

outcome of the decision of HHS, and a summary of any action taken by Congress that affected the outcome of the HHS decision or its implementation. OCAS should prepare and submit the report to the NIOSH Office of the Director a minimum of 21 days prior to the expiration of the 180 day congressional review period. This deadline applies whether or not Congress is actively considering the HHS decision at such time. If Congress concludes its consideration of the HHS decision prior to such time, OCAS should prepare the report as soon as possible.

6.13.2. HHS must approve the report after confirmation of congressional action or after the expiration of the 180 day congressional review period, if Congress does not take action. This report must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s).

6.13.3. Transmit the redacted and OGC-cleared report to the petitioner(s) and the unredacted version of the report to DOL within five work days of either expiration of the congressional review period or notification of final congressional action, whichever comes first.

6.13.4. Post the approved redacted and OGC-cleared report on the OCAS Web Page.

6.13.5. Prepare and publish a Federal Register notice including the report. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.13.6. Provide the Federal Register notice, and other assistance as necessary, to the NIOSH Public Affairs Officer to assist HHS in publicizing the final decision through appropriate media outlets.

6.13.7. Work with DOL, DOE, and other organizations to publicize the report.

6.14. Review the utility of newly obtained records and information for classes of employees added to the cohort

Note: Steps and procedures to provide guidance related to § 83.18, which addresses how the Secretary can cancel or modify a final decision to add a class of employees to the Cohort, will be established at such time as they become necessary. At this time, the only activity required of OCAS and its technical contractor is to monitor the identification and collection of records and information by OCAS to determine their relevance to classes added to the Cohort by HHS.

6.14.1. OCAS and technical contractor staff should notify the Health Science Administrator when records are identified that are relevant to a class of employees added to the Cohort.

Appendix A-Standard notification letter and the SEC Evaluation Process Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

SEC Tracking Number: XXXX

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998
Phone: 513-533-6800
Fax: 513-533-6817

September 22, 2004

Petitioner Name
Address
City/State/ZIP

Dear Petitioner Name:

This letter is to inform you that the National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) has completed the qualification process for you petition, SEC XXXXX. NIOSH has determined that your petition qualifies for evaluation for inclusion into the Special Exposure Cohort (SEC).

The evaluation process begins with this notification to you and the Advisory Board of Radiation and Worker Health (the Board). In addition, a summary of your petition will be posted on the OCAS web site (http://www.cdc.gov/niosh/ocas). The evaluation process focuses on determining whether enough information is available to support dose reconstruction, if possible, through evaluation of existing records and documents currently in NIOSH possession. In some cases, we will also request data from the Department of Energy, an Atomic Weapons Employer, or from other sources, balancing our need for information against the need for a timely consideration and evaluation of the petition. In cases in which we were to determine that there is not sufficient information to support dose reconstruction, we would also evaluate the degree of potential health endangerment.

When we have completed the evaluation, we will provide you with a copy of the evaluation report, which will be considered by the Board during its review. You will be invited to present to the Board during its review, should you so desire. (Your participation in the Board review is entirely voluntary.) After the Board makes a recommendation concerning your petition, the Director of NIOSH will propose a decision of whether or not to add one or more classes of employees to the SEC based upon your petition. The Secretary of Health and Human Services will make final determinations on these matters after further opportunity for you to contest any proposed decision to deny adding a class to the Cohort or concerning a health endangerment determination. If the Secretary of HHS designates a class to be added to the SEC, the class will be added after 180 days, unless Congress acts beforehand either to reverse or expedite the decision.

Appendix A (continued)

During the evaluation process, if you have any questions regarding your petition, please contact OCAS toll-free at 1-800-35-NIOSH (1-800-356-4674), directly at 513-533-6800, or by email at ocas@cdc.gov. You can also contact our contractor toll-free at 1-800-322-0111. Additional information about OCAS and the SEC procedure can be found on the OCAS web site at http://www.cdc.gov/niosh/ocas.

Sincerely,

Larry J. Elliott, MSPH, CIH
Director
Office of Compensation Analysis and Support

Appendix B – DOE Request for Monitoring and Related Records

Personal Monitoring Records

Do you have personal internal and external monitoring records for individuals that worked at DOE/AWE facility during this time period and meet the following conditions? *(include specific class criteria identified in the petition)*

If so, please submit the monitoring data and employment history requested below for _____ (sample) individuals that worked at DOE/AWE facility during that time period.

Subject and employment information, including:

(A) DOE and/or AWE employment history, including: job title held by year, and work location(s): including site name(s), building number(s), technical area(s), and duration of relevant employment or tasks.

External dosimetry data, including:

(A) External dosimeter readings (film badge, TLD, neutron dosimeters)
(B) Pocket ionization chamber data

Internal dosimetry data, including:

(A) Urinalysis results
(B) Fecal sample results
(C) In Vivo measurement results
(D) Incident investigation reports
(E) Breath radon and/or thoron results
(F) Nasal smear results
(G) External contamination measurements
(H) Other measurement results applicable to internal dosimetry

Monitoring program data, including:

(A) Analytical methods used for bioassay analyses
(B) Performance characteristics of dosimeters for different radiation types
(C) Historical detection limits for bioassay samples and dosimeter badges
(D) Bioassay sample and dosimeter collection/exchange frequencies
(E) Documentation of record keeping practices used to record data and/or administratively assign dose

Appendix B – DOE Request for Monitoring and Related Records (continued)

If requested by a check-mark here (___), provide the following information, as available:

Area monitoring data for the covered time period and locations indicated, including:

(A) General area airborne radioactivity sample data,
(B) General area radiation monitoring data,
(C) Location samples taken with respect to equipment/facility layout, and
(D) If available, equipment status (e.g., air sample north of #1 F machine while machine operating),

Source term data, including:

(A) Isotopes used at the facility during the indicated time period,
(B) Chemical form,
(C) Particle size or description (e.g., dry powder),
(D) Capacities of tanks, equipment, and process piping,
(E) Facility layout, Process Description, Process flow diagrams, Mass balance sheets, and
(F) Production rates and inventories.

Any information on exposure incidents which occurred during the identified period, including:

(A) Location,
(B) Duration of the event,
(C) Description of the event,
(D) Description of the radioactive material involved in the event,
(E) Actions taken by site, and
(F) Incident reports.

Appendix C – Evaluation Report Template

Evaluation Summary

This section should fully define the class or classes covered by the evaluation, summarize findings of feasibility and, when appropriate, health endangerment applicable to the class or classes, and briefly summarize the criteria and findings supporting the findings. This section should not explicitly recommend the addition of a class to the Cohort or the denial of the petition, since we want the benefit of the Board's evaluation before we make such a recommendation on behalf of HHS.

Class Definition Proposed by the Petitioner(s) and Petition Basis

This section should identify the class definition proposed by the petitioner and explain with reasonable detail the basis for the petition.

Data Collection

This section, should describe the data collection effort and its results. It should provide information on the following:

- *Specifically which resources of information did we query (through DOE, DR records, research records, and/or from other resources, whether queried specifically in response to this petition or through TBD development or DRs, however the case might be)?*
- *What information germane to the evaluation of the class did we obtain from each resource we queried? (These summaries might be organized under each providing resource according to the hierarchy of information usable for DRs.)*
- *An affirmative statement that we are unaware of any resources of information that we did not query.*
- *When appropriate, we should identify resources of information that were unable to provide data on a timely basis.*

Summary of Radiological Operations Relevant to the Initial Class

This section needs to give the reader a holistic understanding of the work process and exposure potentials in the context of the process, such that the reader can judge whether we have evaluated feasibility (or health endangerment) systematically and completely. This section should give the reader an integrated operational understanding of the industrial process during the relevant timeframe and the radiological elements of this process, characterizing radiation sources, the route(s) of exposure to the class, and protective practices as known. Ideally this section would include narrated graphical depictions of the work process, labeling the various activities and workflow and each important source of potential radiation exposure (e.g., shoveling ore, aerosolized dust from a process, proximity to source term, etc.). If including

graphics were too difficult, the process could be described with a narrative sequence without graphical accompaniment.

Evaluation of Feasibility of Dose Reconstruction

This section should begin with an introduction that summarizes the criteria for determining feasibility and the hierarchical approach NIOSH used to evaluate the adequacy of data for dose reconstruction. It should also explain that this approach was applied to each potential source of radiation exposure for the class (described in detail in the preceding section) to systematically address whether radiation doses could be estimated for all potential sources of radiation exposure to the class.

Then a series of subsections should proceed. Each section should begin by identifying the potential source of exposure, discuss the personal monitoring information and whether it is adequate for DRs based principally on monitoring data; if not, discuss the area monitoring data and whether they, in combination with the personal monitoring data, are adequate; if not, discuss the process and source/source-term data and whether they, in combination with personal and area monitoring data, are adequate. At each level of this analysis, we need to explain why the information is adequate or not adequate.

The section needs to: (a) explain what amount and/or characteristics of data would be adequate to complete DRs for the class using the given level of the hierarchy; and, (b) describe how the data available fall short along these specific parameters.

If data are adequate to support dose reconstruction, we have to explain how such data could be used to reconstruct radiation doses. We should also clearly indicate that actual dose reconstructions for members of the class may employ methods that differ from the methods indicated here to establish feasibility.

If data are not adequate to support dose reconstruction, we must specify criteria that distinguish in bright-line fashion between data that would have been adequate for dose reconstruction and the available data that are not adequate.

Summary of Feasibility Findings

This section should summarize the preceding source-by-source findings of feasibility. A table might be an easy way to do this, the rows being the potential exposure sources and the columns being the determination.

Evaluation of Health Endangerment

When we find DR is not feasible for one or more exposure sources, we need to have a section that addresses health endangerment for those sources. When we determine non-feasibility is

related to a discrete incident, we need to summarize the data, calculations, and findings from the incident and from other comparable incidents, as applicable, that demonstrate the high exposure potential implicated. When NIOSH has not identified exposure incidents that would constitute a discrete incident as defined under 42 CFR § 83.13(c)(3)(i), we need to specify this finding.

Definition of Class

We need a section following the analyses of feasibility and health endangerment that defines the class or classes established on the basis of the analyses. The definition needs to specify the time period, work locations and other employment parameters (e.g., employment duration to address health endangerment when DR is not feasible), using practical terms that could be applied by NIOSH to identify members of a class that has already been considered or by DOL to identify members of a class that could be added to the Cohort. This section also needs to identify and provide rationale for any changes made by NIOSH to the petitioner-proposed class definition as a result of the evaluation.